Lube-Tech
PUBLISHED BY LUBE: THE EUROPEAN LUBRICANTS INDUSTRY MAGAZINE
No.64 page 1

FATIGUE and COMPLEXITY
The next stage of REACH

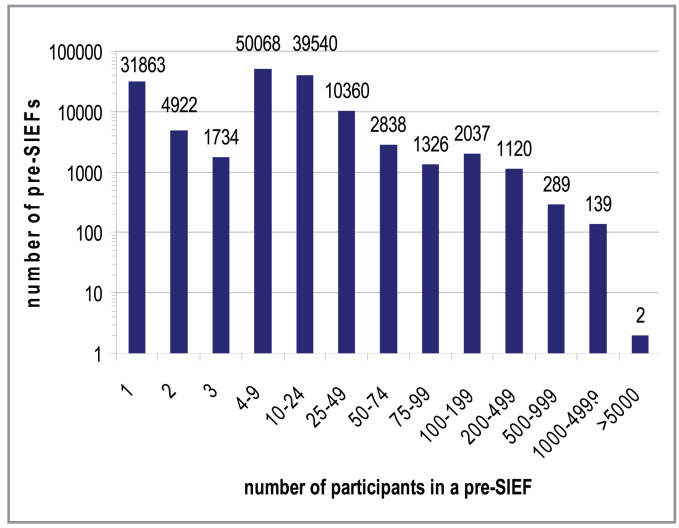
As is widely known, the substance pre-registration period of REACH ended on 1 December 2008. It was anticipated by the legislators that the next phase would begin almost immediately – the formation of SIEFs (Substance Information Exchange Forums). However, the reality was far from the truth. Confusion, pre-registration fatigue, complexity and lack of clarity with the process took its toll, and the waiting game started. Who would blink first? Inevitably it was the larger companies with the necessary resources and understanding who began to kickstart the process. They could see the first registration date of 1 December 2010 looming for substance manufactured or imported in volumes greater than 1000 tonnes per annum.

SIEFs are legally mandated in the REACH legislation. Their purpose is to bring together companies who pre-registered the same substance so that existing (mainly vertebrate animal) data are shared, potential data gaps identified, and new studies commissioned only once and not duplicated. These will then be used for the registration of the substance by the Lead Registrant in the SIEF, approximately 6 months in advance of the appointed date. The other members will then submit their own dossiers that refer to the common dossier of the lead registrant and provide additional information that is company-specific, including references to the experimental data already submitted. Other tasks of the SIEF are to agree the hazard classification of the substance (which is also mandatory under the new European Classification, Labelling & Packaging regulation – the EU transposition of GHS - for substances by the same 1 December 2010 deadline as the REACH first wave registration), and to prepare robust summaries of existing data.

Some SIEFs have only a few members, but for many substances the membership can run into hundreds and in some cases, thousands of legal entities (See Figure 1). A further complication is that existing or new industry consortia are overseeing the data gathering for substances of interest, and these consortia can span a number of SIEFs. Consortia have no legal standing under REACH. Overall then, is it no wonder that the organisational challenges involved in SIEF formation appear to be overwhelming?

The REACH-IT system for pre-registration permitted a pre-registrant to indicate if he wanted to act as an SFF (SIEF Formation Facilitator) for the substance. This is not an official

Figure 1



role, but is seen as a way of initiating and managing the activities of the SIEFs. However, for many thousands of substances, no SFFs were identified or the self-appointed SFF has failed to begin the process, or has not followed up on initial communications. In a number of cases other companies or consortia have stepped in to bring order from chaos to get the ball rolling. For the smaller companies who may not have such a deep understanding of REACH, the situation must appear bewildering. This is not so much a problem at the moment for substances due for registration in 2018, but for 2013 (and particularly 2010) registrations, time is not our side and the affected companies may wish to contact others who pre-registered the same substance to find out what is going on, if no SIEF has been formed yet.

CEFIC (the European chemical industry's association) has recently published a document offering advice to companies on how to work around any obstacles to SIEF progress. A number of other organisations have also prepared similar publications giving assistance for SIEF formation.

Concurrent with SIEF activity is that of building Exposure Scenarios (ES) across the different supply chains for all identified uses. Here, at least in the lubricant sector, there is more clarity. ES's are required for substances (and substances in formulated products) that fulfil certain criteria - > 10 tpa, classified as dangerous for supply, or PBT/vPvB. An Exposure Scenario is 'the